

1 CLAIMS

2 What is Claimed Is:

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4 Claim 1. A method for treating a patient suffering from a cancerous disease
5 comprising:

6 administering to said patient an anti-cancer antibody or fragment thereof produced
7 in accordance with a method for the production of anti-cancer antibodies which are useful
8 in treating a cancerous disease, said antibody or fragment thereof characterized as being
9 cytotoxic against cells of a cancerous tissue, and being essentially benign to non-cancerous
10 cells;

11 wherein said antibody or fragment thereof is placed in admixture with a
12 pharmaceutically acceptable adjuvant and is administered in an amount effective to
13 mediate treatment of said cancerous disease;

14 said antibody being an isolated monoclonal antibody or antigen binding fragment
15 thereof which binds to an antigenic moiety expressed by said cancerous tissue, said
16 antigenic moiety characterized as being bound by an antibody having identifying
17 characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as
18 PTA-4621.

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20 Claim 2. The method for treating a patient suffering from a cancerous disease
21 in accordance with claim 1, wherein said antibody or fragment thereof is humanized or
22 chimerized.

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2 Claim 3. The method for treating a patient suffering from a cancerous disease
3 in accordance with claim 1 comprising:

4 conjugating said antibody or antigen binding fragment thereof with a member
5 selected from the group consisting of toxins, enzymes, radioactive compounds, and
6 hematogenous cells, thereby forming an antibody conjugate; and

7 administering said antibody conjugate or conjugated fragments thereof to said
8 patient;

9 wherein said antibody conjugate or conjugated fragments are placed in admixture
10 with a pharmaceutically acceptable adjuvant and are administered in an amount effective to
11 mediate treatment of said cancerous disease.

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13 Claim 4. The method of claim 3, wherein said antibody or fragment thereof is
14 humanized or chimerized.

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16 Claim 5. The method for treating a patient suffering from a cancerous disease in
17 accordance with claim 1 wherein:

18 the cytotoxicity of said antibody or fragment thereof is mediated through antibody
19 dependent cellular toxicity.

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21 Claim 6. The method for treating a patient suffering from a cancerous disease in
22 accordance with claim 1 wherein:

1 the cytotoxicity of said antibody or fragment thereof is mediated through
2 complement dependent cellular toxicity.

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4 Claim 7. The method for treating a patient suffering from a cancerous disease in
5 accordance with claim 1 wherein:

6 the cytotoxicity of said antibody or fragment thereof is mediated through catalyzing
7 of the hydrolysis of cellular chemical bonds.

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9 Claim 8. The method for treating a patient suffering from a cancerous disease in
10 accordance with claim 1 wherein:

11 the cytotoxicity of said antibody or fragment thereof is mediated through producing
12 an immune response against putative cancer antigens residing on tumor cells.

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14 Claim 9. The method for treating a patient suffering from a cancerous disease in
15 accordance with claim 1 wherein:

1 the cytotoxicity of said antibody or fragment thereof is mediated through
2 targeting of cell membrane proteins to interfere with their function.

3

4 Claim 10. The method for treating a patient suffering from a cancerous disease
5 in accordance with claim 1 wherein:

6 the cytotoxicity of said antibody or fragment thereof is mediated through
7 production of a conformational change in a cellular protein effective to produce a
8 signal to initiate cell-killing.

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10 Claim 11. The method for treating a patient suffering from a cancerous
11 disease in accordance with claim 1 wherein:

12 said method of production utilizes a tissue sample containing cancerous and
13 non-cancerous cells obtained from a particular individual.

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15 Claim 12. A method for treating a patient suffering from a cancerous
16 disease comprising:

17 administering to said patient an antibody or antigen binding fragment thereof
18 produced in accordance with a method for the production of anti-cancer antibodies
19 which are useful in treating a cancerous disease, said antibody being cytotoxic against
20 cells of a cancerous tissue, and essentially benign to non-cancerous cells;

21 wherein said antibody is the isolated monoclonal antibody encoded by the clone
22 deposited with the ATCC as PTA-4621 or an antigen binding fragment thereof, and is

1 placed in admixture with a pharmaceutically acceptable adjuvant and is administered in
2 an amount effective to mediate treatment of said cancerous disease.

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4 Claim 13. The method for treating a patient suffering from a cancerous
5 disease in accordance with claim 12, wherein said antibody or fragment thereof is
6 humanized or chimerized.

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8 Claim 14. The method for treating a patient suffering from a cancerous
9 disease in accordance with claim 12 comprising:

10 conjugating said antibody or fragment thereof with a member selected from the
11 group consisting of toxins, enzymes, radioactive compounds, and hematogenous cells,
12 whereby an antibody conjugate is formed; and

13 - administering said antibody conjugates or fragments thereof to said patient;

14 wherein said conjugated antibodies are placed in admixture with a
15 pharmaceutically acceptable adjuvant and are administered in an amount effective to
16 mediate treatment of said cancerous disease.

17 Claim 15. The method of claim 14, wherein said antibody or fragment
18 thereof is selected from said subset are humanized or chimerized.

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20 Claim 16. The method for treating a patient suffering from a cancerous disease
21 in accordance with claim 12 wherein:

1 the cytotoxicity of said antibody or fragment thereof is mediated through
2 antibody dependent cellular toxicity.

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4 Claim 17. The method for treating a patient suffering from a cancerous disease
5 in accordance with claim 12 wherein:

6 the cytotoxicity of said antibody or fragment thereof is mediated through
7 complement dependent cellular toxicity.

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9 Claim 18. The method for treating a patient suffering from a cancerous disease
10 in accordance with claim 12 wherein:

11 the cytotoxicity of said antibody or fragment thereof is mediated through
12 catalyzing of the hydrolysis of cellular chemical bonds.

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14 Claim 19. The method for treating a patient suffering from a cancerous disease
15 in accordance with claim 12 wherein:

16 the cytotoxicity of said antibody or fragment thereof is mediated through
17 producing an immune response against putative cancer antigens residing on tumor
18 cells.

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20 Claim 20. The method for treating a patient suffering from a cancerous disease
21 in accordance with claim 12 wherein:

1 the cytotoxicity of said antibody or fragment thereof is mediated through
2 targeting of cell membrane proteins to interfere with their function.

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4 Claim 21. The method for treating a patient suffering from a cancerous disease
5 in accordance with claim 12 wherein:

6 the cytotoxicity of said antibody or fragment thereof is mediated through
7 production of a conformational change in a cellular protein effective to produce a
8 signal to initiate cell-killing.

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10 Claim 22. The method for treating a patient suffering from a cancerous
11 disease in accordance with claim 12 wherein:

12 said method of production utilizes a tissue sample containing cancerous and
13 non-cancerous cells obtained from a particular individual.

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15 Claim 23. A process for mediating cytotoxicity of a human tumor cell
16 which expresses a CD44 antigenic moiety on the cell surface comprising:

17 contacting said tumor cell with an isolated monoclonal antibody or
18 antigen binding fragment thereof, said antibody or antigen binding fragment thereof
19 being an isolated monoclonal antibody or antigen binding fragment thereof which
20 binds to said expressed CD44 antigenic moiety, said antigenic moiety characterized as
21 being bound by an antibody having the identifying characteristics of a monoclonal
22 antibody encoded by the clone deposited with the ATCC as PTA-4621,

1 whereby cell cytotoxicity occurs as a result of said binding.

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3 Claim 24. The process of claim 23 wherein said isolated antibody or
4 antigen binding fragments thereof are humanized or chimerized.

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6 Claim 25. The process of claim 23 wherein said isolated antibody or
7 antigen binding fragments thereof are conjugated with a member selected from the
8 group consisting of cytotoxic moieties, enzymes, radioactive compounds, and
9 hematogenous cells, whereby an antibody conjugate is formed..

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11 Claim 26. The process of claim 23 wherein said isolated antibody or
12 antigen binding fragments thereof are humanized or chimerized.

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14 Claim 27. The process of claim 23 wherein said isolated antibody or
15 antigen binding fragments thereof are murine.

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17 Claim 28. The process of claim 23 wherein the human tumor tissue sample
18 is obtained from a tumor originating in a tissue selected from the group consisting of
19 colon, ovarian, lung, prostate and breast tissue.

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21 Claim 29. A binding assay to determine a presence of cells which express a
22 CD44 antigenic moiety which specifically binds to an isolated monoclonal antibody

1 encoded by the clone deposited with the ATCC as PTA-4621 or an antigen binding
2 fragment thereof comprising:
3 providing a cell sample;
4 providing an isolated monoclonal antibody or antigen binding fragment thereof,
5 said antibody or antigen binding fragment thereof being an isolated monoclonal
6 antibody or antigen binding fragment thereof which binds to said expressed CD44
7 antigenic moiety, said antigenic moiety characterized as being bound by an antibody
8 having the identifying characteristics of a monoclonal antibody encoded by the clone
9 deposited with the ATCC as PTA-4621;
10 contacting said isolated monoclonal antibody or antigen binding fragment
11 thereof with said cell sample; and
12 determining binding of said isolated monoclonal antibody or antigen binding
13 fragment thereof with said cell sample;
14 whereby the presence of cells which express a CD44 antigenic moiety which
15 specifically binds to said isolated monoclonal antibody or antigen binding fragment
16 thereof is determined.

17 Claim 30. The binding assay of claim 29 wherein the cell sample is
18 obtained from a tumor originating in a tissue selected from the group consisting of
19 colon, ovarian, lung, prostate and breast tissue.

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21 Claim 31. A process of isolating or screening for cells in a sample which
22 express a CD44 antigenic moiety which specifically binds to an isolated monoclonal
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1 antibody or antigen binding fragment thereof, said antigenic moiety characterized as
2 being bound by an antibody having the identifying characteristics of a monoclonal
3 antibody encoded by the clone deposited with the ATCC as PTA-4621 comprising:
4 providing a cell sample;
5 providing an isolated monoclonal antibody or antigen binding fragment thereof,
6 said antibody or antigen binding fragment thereof being an isolated monoclonal
7 antibody or antigen binding fragment thereof which binds to said expressed CD44
8 antigenic moiety, said antigenic moiety characterized as being bound by an antibody
9 having the identifying characteristics of a monoclonal antibody encoded by the clone
10 deposited with the ATCC as PTA-4621;
11 contacting said isolated monoclonal antibody or antigen binding fragment
12 thereof with said cell sample; and
13 determining binding of said isolated monoclonal antibody or antigen binding
14 fragment thereof with said cell sample;
15 whereby said cells which express a CD44 antigenic moiety which specifically
16 binds to an isolated monoclonal antibody encoded by the clone deposited with the
17 ATCC as PTA-4621, or antigen binding fragment thereof are isolated by said binding
18 and their presence in said cell sample is confirmed.

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20 Claim 32. The process of claim 31 wherein the cell sample is obtained
21 from a tumor originating in a tissue selected from the group consisting of colon,
22 ovarian, lung, prostate and breast tissue.

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2 Claim 33. A method of extending survival and/or delaying disease progression
3 by treating a human tumor in a mammal, wherein said tumor expresses an antigen
4 which specifically binds to a monoclonal antibody or antigen binding fragment thereof
5 which has the identifying characteristics of a monoclonal antibody encoded by a clone
6 deposited with the ATCC as accession number PTA-4621 comprising administering to
7 said mammal said monoclonal antibody in an amount effective to reduce said
8 mammal's tumor burden, whereby disease progression is delayed and/or survival is
9 extended.

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11 Claim 34. The method of claim 33 wherein said antibody is conjugated to a
12 cytotoxic moiety.

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14 Claim 35. The method of claim 33 wherein said cytotoxic moiety is a
15 radioactive isotope.

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17 Claim 36. The method of claim 33 wherein said antibody activates complement.

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19 Claim 37. The method of claim 33 wherein said antibody mediates antibody
20 dependent cellular cytotoxicity.

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22 Claim 38. The method of claim 33 wherein said antibody is a murine antibody.

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1 Claim 39. The method of claim 33 wherein said antibody is a humanized
2 antibody

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4 Claim 40. The method of claim 33 wherein said antibody is a chimerized
5 antibody.

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